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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Thomas Zelinski

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

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1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,427	Applicant(s) ZELINSKI ET AL.	
	Examiner SUSAN HANLEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 19, 22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20, 21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 14-21 and 23 and the microorganism specie, Alkalifies, and fine chemical specie in the reply filed on 2/1/08 is acknowledged. It is noted that the lack of unity requirement inadvertently put claims 25 and 26 with both Groups I and IV. The examiner apologizes for the typographical mistake and points out that it was clear from the first paragraph of page 4 of the lack of unity reasons (which demonstrated the lack of a special technical feature between Group I and Group IV) that claims 25 and 26 were intended only to belong with Group IV.

The traversal is on the ground(s) that Groups I-IV share the common special technical feature of preserving and/or storing a microorganism which exhibits at least one nitrilase enzyme activity. Regarding groups I, III and IV, Applicant argues that Kobayashi does not teach said special technical feature. Applicant concludes that the Office has not established a lack of unity because since the special technical feature defines a contribution which the claimed invention makes over the prior art.

Applicant asserts that the examiner has used the rationale applicable to U.S. restriction practice and has not applied the required standard lack of unity of invention regarding Group II and III; Group I, II and IV; and Groups I and IV. Applicant asserts that Groups I-IV all related to preserving and/or storing microorganisms which exhibit at least one nitrilase activity.

Applicant argues that there is no serious burden on the examiner to search and examine all of the groups together because Groups I-IV share a special technical feature. Applicant requests that at least Groups I and II be examined together because Group II merely discloses measures to

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perform the method of Group I. Applicant further asserts that there is no evidence of a search burden because the unity of invention was found during the international stage and a search was conducted on all of the claims.

This is not found persuasive. Responding to Applicant's arguments regarding the lack of unity of Group III to Groups I and IV and the citation of Kobayashi, Kobayashi teaches the special technical feature of the invention of Group III which is a pharmaceutical agent, nicotinic acid which is a chemical. The special technical feature of nicotinic acid is the structure and properties of the compound which are irrespective of its source. Thus, the special technical feature of Group III of group III is disclosed by the prior art and unity is lacking with Groups I and IV.

Responding to Applicant's argument that the examiner has used a rationale that is related to U.S. restriction practice rather than the lack of unity standard required for the National Stage of a 371 application for Group II and III; Group I, II and IV; and Groups I and IV and that all of Groups I-IV all related to preserving and/or storing microorganisms which exhibit at least one nitrilase activity, this is incorrect. The special technical feature of each group was determined and compared with the special technical feature of the other groups. As pointed out in the restriction requirement, the special technical feature of each group is not the preservation and/or storage of microorganisms which exhibit at least one nitrilase activity. Unity of invention requires that the groups have a common or shared special technical feature. The lack of a shared technical feature among the indicated groups was explained in each case. It is noted that Applicant has failed to directly address each of these relationships.

Responding to Applicant's argument that there is no serious search burden, searching requires a review of extensive and multitudinous records in the various and appropriate commercial

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databases and places a serious burden on the examiner if forced to search and examine both inventions. It is also noted that the search is not merely limited to narrow aspects of the prior art, but also is necessary for the Examiner to make appropriate determinations as to the enablement and clarity of the claims in view of the specification.

Responding to Applicant's request that Groups I and II be examined together, lack of unity was properly demonstrated. Applicant's argument is unpersuasive because it fails to address the basis of the finding of the lack of a shared special technical feature. Group II comprises a solution having two compounds. This invention lacks a special technical feature in common with Group I because said solution is simply a mixture of chemicals while other said groups require a microorganism which is a complex living organism comprising many different molecules (e.g., lacks DNA, proteins, etc.) which interacts with aldehydes, etc. There is no commonality of a shared special technical feature.

Responding to Applicant's argument that there is no search burden because the ISA found lack of unity, any findings by the ISA are respected but not binding in any way on U.S. patent practice.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19, 22 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/1/08. Claim 19 is withdrawn from further consideration because the expected specie from claim 20, *Alcaligenes*, is in the family *Alcaligenaceae* which is not claimed in instant claim 19.

Claims 14-18, 20, 21 and 23 and the *Alcaligenes* specie are presented for examination.

Claim Suggestions

It is suggested that claim 17 be reworded to following: A method according to claim 14, wherein the aqueous medium comprises at least one cyanide compound selected from the group consisting of nitriles,, wherein the total concentration of said cyanide compound is at most 10 mol% of the total aldehyde concentration or wherein the aqueous medium does not comprise the addition of said cyanide compound.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-18, 20, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Claim 14 does not recite a step that requires an action that results in a result. It consists of a preamble and limitations regarding the aldehyde concentration. The claim lacks a step directed to contacting a microorganism with an aqueous medium comprising at least one aldehyde.

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Claims 14 is rejected because the units for the concentration of the aldehyde are confusing. concentration is expressed as "mM/l". this does not correspond with any standard units for concentration.

Claim 15 is rejected because the term "hetaryl" is not a recognized term of organic nomenclature and it is not defined.

Claim 20 is rejected because the claim designates genera and not species, i.e., *Pseudomonas* is a genus.

Claim 21 is rejected because the phrase "one further method" renders the claim vague and indefinite. It is unclear if the claim is reciting a further step for stabilizing, preserving and/or storing enzymes or if a method distinct from claim 14 is being claimed.

The term "stabilizing" in line 2 of claim 21 lacks antecedent basis in claim 14.

Claims 15-18, 21 and 23 are dependent claims that do not overcome the deficiencies of the independent claim that they are dependent therefrom.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-18, 20, 21 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yamaguchi et al. (EP 773,297; cited in the IDS filed 9/8/05).

Yamaguchi discloses a process for producing alpha-hydroxyamides or alpha-hydroxy acids by reacting a microorganism having nitrilase activity with a substrate in the presence of a mixture of a mixture of an aldehyde and prussic acid (synonym for hydrogen cyanide). Yamaguchi teaches that any microorganism that is capable of carrying out the reaction to produce the disclosed product(s) are suitable for carrying out the reaction. Yamaguchi discloses a number of suitable microorganisms (p. 4, [0014] to [0019]) and selects a group of seven particular strains including *Alcaligenes* sp. (BC16-2) for performing the reaction. This group of seven microorganisms is small and well-defined. Hence, it is deemed to anticipate the claimed *Alcaligenes* microorganism, as in instant claim 20. Yamaguchi teaches suitable aldehydes such as benzaldehyde (page 4, [0020] to p. 5, [0024]), as in instant claims 15 and 18. The concentration of the aldehyde is in the range of 0.01 to 1,000 mM, 0.05 to 200 mM or 1 to 50 mM (p. 3 [0009]. The final concentration of 1 to 50 mM partly overlaps the claim range of 0.1 to 100 mM in, this anticipating claim 14. In example 11, Yamaguchi discloses an embodiment wherein 20 mM of buffer and a microorganism were charged to a reactor. "After adding benzaldehyde thereto and dissolving the same so as to provide a concentration of 30 mM, prussic acid and benzaldehyde starting material were supplied to the reactor while controlling the molar concentration of 1.0:1.02" (bottom of page 6). Therefore, the microorganism is contacted with 30 mM benzaldehyde before the addition of the mixture of the further benzaldehyde (which is identified as the reactant) and prussic acid. This meets the limitations of claim 14, 15 and 18 because benzaldehyde at 30 mM is contacted with a microorganism. The disclosure meets the limitation of claim 16 because the initial amount of benzaldehyde is not identified as a reactant. The addition of prussic acid, a nitrile, meets the limitation of claim 21. The limitations of claim 23 are satisfied because there is a composition that consists of buffer,

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microorganism and benzaldehyde (prior to the addition of the prussic acid). This composition contains no nitrile. Thus, the limitations of claims 23 for the preparation is met. It is noted in claims 17 and 23 that there is no limitation as to the length of time that the microorganism/aldehyde composition is free of nitrile.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651

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